UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

IN RE: FRESENIUS GRANUFLO/NATURALYTE DIALYSATE PRODUCTS LIABILITY LITIGATION	:	**MDL NO. 1:13-MD-2428-DPW**
This Document Relates to:	:	
All Cases	:	

FMCNA'S OPPOSITION TO PLAINTIFFS' MOTION TO ENFORCE THIRD PARTY SUBPOENA AND COMPEL USE OF ADDITIONAL SEARCH TERMS AND PRODUCTION OF DOCUMENTS

Defendants Fresenius Medical Care Holdings, Inc. d/b/a Fresenius Medical Care North America, Fresenius USA, Inc., Fresenius USA Manufacturing, Inc., Fresenius USA Marketing, Inc., and Fresenius USA Sales, Inc. (collectively, "FMCNA") oppose Plaintiffs' Motion to Enforce Third Party Subpoena and Compel Use of Additional Search Terms and Production of Documents.

FMCNA has, to date, produced approximately 134,500 pages of emails and attachments of its consultant, Dr. Gotch, in response to a Request for Production of Documents served on FMCNA. In addition, FMCNA has produced over 38,000 pages of responsive, non-privileged documents maintained by Dr. Gotch, and expects to produce an additional 250,000 pages of documents by the end of the week. All of the produced documents were identified by applying the 12 agreed-upon search terms negotiated by the parties last May.

Plaintiffs now ask this Court to compel FMCNA to run additional search terms against computer laptops and hard copy materials collected from the home of Dr. Gotch, to perform a further manual, page-by-page responsiveness review of the 58 boxes of materials that were collected in hard copy, and to produce a log detailing all documents withheld, whether on privilege *or responsiveness* grounds. In support of this extraordinary request, Plaintiffs assert

that Dr. Gotch is the principal proponent of a "novel" theory crafted for purposes of avoiding liability in this litigation, that FMCNA inappropriately wrested control of the vast collection of materials that Dr. Gotch maintained in his home, and that FMCNA is now refusing to produce relevant documents from that collection. Each of these assertions is manifestly inaccurate.

Far from being a "novel" litigation strategy, FMCNA's position regarding the impact of dialysis treatment on a patient's serum bicarbonate levels is premised on the fundamental and long-proven scientific principle of diffusion, which is the very mechanism that makes dialysis possible at all. Dr. Gotch was certainly not an architect of this basic scientific principle. Rather, as explained below, Dr. Gotch simply confirmed that the concept of "total buffer" to which FMCNA previously subscribed failed to account properly for the operation of the diffusion principle and was, therefore, incorrect.

Moreover, the facts belie Plaintiffs' attempt to paint a nefarious picture of the course of action that FMCNA took to further gather and preserve Dr. Gotch's documents. Specifically, in September 2014, FMCNA accepted a third-party subpoena on behalf of Dr. Gotch and offered to provide him with representation in his capacity as an FMCNA consultant. Dr. Gotch accepted this offer. Shortly thereafter, Dr. Gotch's counsel learned from his wife that, at age 88, Dr. Gotch was displaying early symptoms of Alzheimer's Disease and may be unable to testify in this litigation. With that knowledge, Dr. Gotch's counsel visited Dr. Gotch and his wife in their home to discuss the matter in more detail. In order to prepare for the likelihood that Dr. Gotch would not be able to provide testimony, his counsel requested and received permission to capture the contents of each of Dr. Gotch's computers and to copy the entirety of Dr. Gotch's medical and scientific library—58 boxes of materials. Notably, Dr. Gotch had a distinguished sixty-year career in the field of nephrology and he provided consulting services to FMCNA on myriad

topics for many years. Thus, despite Plaintiffs' protestations to the contrary, there can be no dispute that the vast collection of materials in Dr. Gotch's library consists largely, if not primarily, of documents that are wholly unrelated to the subject matter of this litigation. Plaintiffs concede that FMCNA has already produced documents on behalf of Dr. Gotch responsive to the set of twelve search terms that the parties agreed were sufficient to capture documents relevant to this litigation. Under such circumstances, Plaintiffs cannot credibly claim that they have been denied access to relevant documents with respect to Dr. Gotch, much less can they set forth sufficient reason to justify the costly and time-intensive request that they have made. Accordingly, Plaintiffs' motion should be denied.

BACKGROUND

Plaintiffs' motion to compel begins with a lengthy explication of Plaintiffs' version of the key events at issue in this case. According to Plaintiffs, FMCNA's NaturaLyte and GranuFlo products are dangerous because they cause patients to receive an unexpectedly high dose of "total buffer" during hemodialysis. Plaintiffs assert this must be so because (1) diffusion during hemodialysis is "junk science" not supported by peer-reviewed data; (2) treating nephrologists do not realize that a properly functioning liver can metabolize acetate into bicarbonate; and (3) NaturaLyte and GranuFlo deliver "extra" or "excess" bicarbonate that causes patients to receive a bicarbonate dose above that prescribed by the treating nephrologist. None of these assertions is true. To the contrary: (1) diffusion is universally recognized as the operative principle upon which hemodialysis therapy is based; (2) hemodialysis therapy relied for many years on the medical fact that the liver metabolizes acetate to bicarbonate and this fact is recounted in the most basic guides for physicians and clinics; and (3) NaturaLyte and GranuFlo are acid

concentrates which do not add bicarbonate during dialysis beyond the dialysate solution prescribed by the treating physician.

I. Diffusion Across The Dialyzer Membrane Is The Fundamental Basis Of Hemodialysis Therapy.

The therapeutic aspect of hemodialysis takes place as a patient's blood moves through a dialyzer cartridge containing a bundle of thousands of hollow fibers resembling straws of microscopic diameter. The walls of the hollow fibers are semi-permeable membranes. The blood flows in one direction inside the hollow fibers. Liquid dialysate flows in the opposite direction on the outside of the hollow fibers. The semi-permeable membrane comprising the wall of the hollow fiber is designed so that its pores are too small for red blood cells to leak out of the tubes, but large enough to allow water, as well as urea and other toxins, to move out of the blood, through the membrane, and into the dialysate. Conversely, the membrane allows important electrolytes such as potassium, calcium, magnesium and bicarbonate contained in the dialysate solution to transport though the membrane and into the blood.

Nephrologists have recognized for decades that diffusion of these various molecules across the membrane is driven by differences in the molecular concentration between the blood and the dialysate. If, for instance, the concentration of calcium in the dialysate exceeds the concentration of calcium in the blood, calcium molecules will pass through or over the membrane from the dialysate into the blood. As the concentration approaches equilibrium, the rate of transport slows. If equilibrium is achieved, transport over the membrane stops. Importantly for this case, the semi-permeable membrane is a two-way street. So in the example above, if the concentration of calcium in the blood were to exceed the concentration of calcium in the dialysate, the direction of transport would reverse, with calcium leaving the blood and moving back into the dialysate. Diffusion resulting from concentration differentials is not a

"theory." It is a basic principal of science validated every day during thousands of successful dialysis treatments. *See* Exhibit A (especially p. 77).

II. In the Early Days Of "Two-Stream" Hemodialysis, Acetate Converted By The Patient's Liver Was The Sole Source Of Bicarbonate Used To Re-Establish A Patient's Acid-Base Balance

Dialysis "cleans" the blood by removing impurities from the blood stream. However, dialysis also provides the body with important electrolytes as well. Indeed, a properly functioning human kidney maintains the body's pH balance and keeps the body in acid-base balance. Thus, one important function of hemodialysis therapy is to re-establish a patient's acid-base balance. Breathing, digesting food proteins, and muscle activity all cause acids to build up in the blood and without a functioning kidney the body has difficulty neutralizing them. Most patients present for dialysis treatment with too much serum acid, making them "acidotic." To correct this state, physicians seek to add bicarbonate to the patient's blood during dialysis treatment to counteract the acids and re-establish proper serum pH levels. Because dialysis takes place only 3 days per week, the treatment must also provide enough bicarbonate stores to allow the patient to continue to neutralize acids until the next dialysis session.

In the 1970s and 1980s, nephrologists employed "two-stream" dialysis machines.[1] These machines delivered dialysate made from a stream of acetate plus electrolytes, mixed with a stream of water. The acetate was delivered at very high concentrations, typically between 37-41 milliequivalents per liter ("mEq/L"). See Exhibit B. Physicians knew that a patient's liver would metabolize at least some of the acetate into bicarbonate once the acetate passed over the dialyzer membrane into the blood. At this time, metabolized acetate was the ***only*** source of bicarbonate used by nephrologists administering hemodialysis therapy to re-establish a patient's

[1] This technique was commonly referred to in the field as "acetate dialysis."

acid-base balance. Plaintiffs' suggestion that nephrologists do not understand or realize that acetate in the dialysate can transport into the patient's blood and be metabolized by the liver into bicarbonate is plainly wrong. Nephrologists used that very process to keep dialysis patients alive for more than two decades and it is still used in other countries today. *See* Exhibit C.

III. All Modern Three-Stream Dialysis Systems Use An Acid Concentrate Containing A Small Amount of Acetate

Some patients did not tolerate the high levels of acetate well, sometimes feeling sick during or following treatment. As a result, beginning in the 1980s, the industry developed what is commonly known today as "three-stream" or "bicarbonate" hemodialysis. With three-stream hemodialysis, the high-concentration acetate stream has been replaced by a stream of pure bicarbonate. However, bicarbonate will not effectively mix with water and the other electrolytes needed for dialysis. In particular, bicarbonate and calcium will precipitate when mixed together with water. To prevent this precipitation and ensure that the dialysate remains entirely liquid, dialysate manufacturers add a small concentration of acid to the dialysate to prevent precipitation. Thus, "three-stream" dialysis consists of a bicarbonate stream, an electrolyte/acid stream, and a stream of water, which all combine to form the dialysate delivered to the patient. During the 1990s, three-stream (bicarbonate) dialysis replaced two-stream (acetate) dialysis as the standard of care. *See* Exhibits C and E.

Plaintiffs' argument that NaturaLyte and GranuFlo are somehow different or unique or contain "extra" ingredients is demonstrably incorrect. All manufacturers of dialysate products offer an acid concentrate that adds a small amount of acetate to the dialysate after the three streams are mixed. *See* Exhibit AG (manufacturers' product offerings and their acetate contribution to the dialysate). Nor are NaturaLyte or GranuFlo new products recently brought to market. In fact, NaturaLyte is one of the ***original*** three-stream acid concentrates, having

received FDA clearances in 1981 and 1985. *See* Exhibits D, E, and F. GranuFlo entered the market in 1993, and received FDA clearances in 1991 and 1994.[2] *See* Exhibits G and H. Like every other acid concentrate product on the market, NaturaLyte and GranuFlo clearly display their acid content on the product labels. *See* Exhibits J and K. Granuflo's acid concentration is far lower than that found in acetate-based dialysate and slightly higher than currently-competing products because it comes in a dry-powder form, both facts reviewed and cleared by the FDA in the early 1990s. NaturaLyte and GranuFlo have been on the market for decades and are still on the market, and have been and are continuing to be used successfully in millions of dialysis treatments. They always have been and continue to be safe and effective products.

IV. "Total Buffer" Is Not A "Generally Accepted Dialysis Concept"; It is a Now-Corrected Mistake

Plaintiffs open their brief with a declaration that "total buffer" is a "generally accepted dialysis concept[.]" Once again, Plaintiffs miss the mark. In the 30 years since three-stream dialysis was introduced, no dialysate manufacturer outside of FMCNA has utilized the "total buffer" concept on a product label; no dialysate manufacturer has included warnings or instructions relating to "total buffer" on any product; and no manufacturer of hemodialysis machines has included a "total buffer" screen on its machine. Investigation of these cases has demonstrated that the concept of "total buffer" is a shorthand expression capable of being misunderstood to such a degree that it should not be used – a fact that Fresenius has discussed with the FDA with the result that the term has been removed from the produce label and is being removed from Fresenius' product literature. It is, of course, true that acetate is a bicarbonate precursor and thus can provide a "buffer" or base to a patient once it is metabolized by the liver.

[2] GranuFlo received an additional 510K clearance in 2003 as the result of a change to production methodology which did not impact its acid formulation or content. *See* Exhibit I.

However, it is not correct to suggest that the acetate and the bicarbonate in the dialysate can be "totaled" with that sum being the "total" amount of buffer provided to the patient during dialysis. No patient data (published or unpublished) exists supporting the theory that the buffer sources can be "totaled" into a substance actually existing in the dialysate or provided to the patient during dialysis, nor has any nephrology organization or journal published research demonstrating that "total buffer" has been generally accepted. The term is vague and subject to misinterpretation.[3]

A. FMCNA Erroneously Adopts Dr. Hakim's Mistaken View Of "Total Buffer"

As described above, dialysis works by diffusion across a membrane. Materials in the dialysate that are at lower concentrations in the blood diffuse from the dialysate to the blood. Materials in the blood that are not in dialysate diffuse from the blood to the dialysate. This process works during dialysis treatment and ideally results in the removal of impurities from the blood and the infusion of needed elements into the blood. Typically, the dialysate contains more acetate and bicarbonate than the blood, causing diffusion of bicarbonate and acetate across the dialyzer membrane and into the blood. When the blood carries the acetate to the liver, the liver metabolizes it into additional bicarbonate.

Beginning around 1999, certain FMCNA employees began using "total buffer" as a short-hand term to describe the small amount of additional bicarbonate that a patient receives as a result of his or her liver metabolizing acetate. In this time period, many patients were

[3] Plaintiffs posed this very question to Dr. Hakim – the principal proponent of "total buffer" – at his recent deposition. He confirmed it is not a commonly accepted term:

Q. (by Mr. Ketterer) But the term total buffer -- now, that's a -- that's a terminology which Dr. Lazarus used and which we see all throughout the documents. Is that a term, total buffer, which is commonly accepted among nephrologists?
MR. HUNTLEY: Object to the form.
THE WITNESS: Not to my knowledge. Of the certainly not before the memo was sent out[.]

presenting for dialysis in an acidotic state. FMCNA's Chief Medical Officer, Dr. Mike Lazarus encouraged treating physicians to make a concerted effort to raise pre-dialysis serum bicarbonate levels among acidotic patients. *See* Exhibit L. FMCNA's products business also began highlighting the fact that GranuFlo contributed slightly more acetate to the dialysate -- 6 or 8 mEq/L -- than competitive products, which typically contributed 4 or 5 mEq/L. *See* Exhibits M and N. Far from "concealing" this information, as Plaintiffs suggest, FMCNA touted GranuFlo's ability to provide additional metabolized bicarbonate to patients in virtually all of its product literature, including literature submitted to FDA. *See* Exhibit M. Indeed, in 2004 FMCNA undertook a study comparing pre-dialysis serum bicarbonate levels of nearly 4800 patients who had switched from its NaturaLyte product to its GranuFlo product. The study demonstrated a small increase in pre-dialysis bicarbonate levels – on average from 22.9 mEq/L to 23.7 mEq/L. FMCNA widely published these results, including in its product literature, in a poster presentation at the ASAIO meeting that year, and in an ASAIO journal abstract. *See* Exhibit O. This abstract can be found on the ASAIO website today.

By about 2005, the short-hand notion of "total buffer" as describing acetate as a small source of additional bicarbonate began to go awry. Dr. Raymond Hakim, who was then-Chief Medical Officer of a dialysis provider called Renal Care Group, became convinced that the prevailing wisdom about patient serum bicarbonate levels was wrong. In particular, Dr. Hakim believed that the KDOQI[4] guideline – which stipulated a ***minimum*** pre-dialysis serum bicarbonate level of 22 mEq/L – was too high. *See* Exhibit P. Dr. Hakim wanted patients to present for dialysis with bicarbonate levels around 20 mEq/L, even though most nephrologists would consider a patient with those levels borderline acidotic. *See* Exhibit Q.

[4] The Kidney Disease Outcomes Quality Initiative is a set of consensus guidelines promulgated by the National Kidney Foundation.

Although he had previously been a supporter of GranuFlo and endorsed its use at RCG, once Dr. Hakim became convinced that patient bicarbonate levels needed to be lowered, he embraced and began advocating for a new and more expansive meaning of "total buffer," especially as it related to GranuFlo. Specifically, Dr. Hakim came to believe that any acetate in the dialysate should be considered, additively, as bicarbonate – in addition to the prescribed bicarbonate present in the dialysate -- since it might later be metabolized into bicarbonate in the patient's body if the liver were functioning properly. *See* Exhibit Q.

So for example, if a nephrologist prescribed bicarbonate of 37 mEq/L and used GranuFlo as the acid concentrate, the hemodialysis machine would deliver a dialysate containing 37 mEq/L bicarbonate and 8 mEq/L acetate. Dr. Hakim promoted a view that in this example, the dialysate would "deliver" a "total bicarbonate" or "total buffer" to the patient of 45 mEq/L. In the same manner, Dr. Hakim concluded that during treatment, acetate that had transported to the blood from the dialysate would metabolize into bicarbonate and ***additively*** combine with the prescribed dialysate bicarbonate, thereby causing the bicarbonate in the patient's blood to exceed the prescribed amount during treatment. So in the example above, Dr. Hakim proposed that the patient would conclude a dialysis session with a serum bicarbonate level of 45 mEq/L.

In early 2006, FMCNA acquired RCG, and Dr. Hakim became an employee in the FMCNA Medical Office. Once inside FMCNA, he continued to advocate that treating nephrologists should be counseled to target levels below the recognized KDOQI minimum. *See* Exhibit R. Dr. Hakim also began pushing his view of "total buffer," and argued that treating nephrologists should begin writing their ***prescriptions*** based on this additive concept of "total buffer." *See id.*

Dr. Hakim's approach to "total buffer" drove his view that patients in general should receive less bicarbonate so that their pre-dialysis serum bicarbonate levels would fall into the much lower range advocated by Dr. Hakim. Dr. Hakim also repeatedly stated that his "real concern" was not simply pre-dialysis serum bicarbonate levels, but rather ***post***-dialysis patient bicarbonate levels, which typically are not measured. Dr. Hakim stated definitively on numerous occasions that because of inappropriately high "total buffer," patients were finishing dialysis in a range of 45-50 mEq/L serum bicarbonate. *See* Exhibit S. Despite the certainty of his previous pronouncements, when asked at his recent deposition if he was aware of any actual patient data demonstrating post-dialysis levels in the ranges he had previously claimed, he consistently answered "I cannot recall." *See* Exhibit S.

Other FMCNA employees adopted Dr. Hakim's version of 'total buffer." Many high-ranking employees both in the Medical Office and in the products group repeated Dr. Hakim's pronouncements. At his direction, FMCNA staff prepared and disseminated educational materials explaining Dr. Hakim's view of "total buffer," including his view that the two sources of bicarbonate are additive and that during dialysis patients can receive an amount of bicarbonate equal to the sum of the acetate and bicarbonate in the dialysate. It is also true that Dr. Hakim's explication of "total buffer" resulted in some confusion among treating nephrologists and nurses, who struggled to understand why they should change a bicarbonate prescription regimen that had been standard in the field for decades.

B. FMCNA And FDA Realize That "Total Buffer" Is a Mistake

In January of 2010, Dr. Hakim became Chief Medical Officer of FMCNA's dialysis services business. This position provided him the opportunity to more forcefully advocate his views concerning patient bicarbonate levels, as well as "total buffer." Dr. Hakim also began

work on a review of FMCNA patient data related to pre-dialysis bicarbonate levels and cardiac arrest. In November of 2011, Dr. Hakim issued a Medical Office Memorandum that pulled together all of his opinions relating to bicarbonate levels. Among other things, the Memorandum stated that:

- There had been a "progressive shift towards higher **pre-dialysis** serum bicarbonate levels," which, in Dr. Hakim's view, implied that "an even higher percentage of patients have alkalosis post-dialysis."

- Dr. Hakim had determined that *"borderline elevated pre-dialysis bicarbonate levels and overt alkalosis are significantly associated with 6 to 8 fold greater risk of CP arrest and sudden cardiac death in the dialysis facility"*. [sic]

- Dr. Hakim believed "[t]he major cause of metabolic alkalosis in dialysis patients is inappropriately high dialysate total buffer concentration."

- Dr. Hakim thought "[t]he bicarbonate prescription entered into the dialysis machine underestimates the total buffer that the patient receives from the dialysate - *by -8 mEq/L in the case of dialysate prepared from Granuflo (powder) or by -4 mEq/L in the case of dialysate prepared from NaturaLyte (liquid)*[.]"

See Exhibit T (emphasis in original).

Someone anonymously provided Dr. Hakim's Memorandum to FDA, which contacted FMCNA because the Memorandum discussed GranuFlo and NaturaLyte, which are FDA regulated products. Based on Dr. Hakim's Memorandum, FDA requested – and FMCNA agreed to – additions to the product labelling and customer notifications that included information about "total buffer." Following these announcements, and primarily based upon the opinions and conclusions offered by Dr. Hakim in his 2011 Memorandum, plaintiffs began filing the lawsuits at issue here.

Initially, FMCNA's defenses focused on the clear errors that a close inspection of the Hakim Memorandum revealed. Specifically, Dr. Hakim failed to adjust the data to account for factors such as malnutrition, which is a known cause of alkalosis. Once the data is adjusted to

account for malnourished patients, the supposed increased risk of cardio-pulmonary arrest that Dr. Hakim reported ***disappears***.[5] As the case progressed, FMCNA focused on the issue of "total buffer" and further closely reviewed the post-dialysis serum bicarbonate test results that had been taken on patients over the years. These post-dialysis test results (including a large number of monthly tests reviewed in 2004 and specific post-dialysis testing conducted in 2007 and 2010) were not consistent with Dr. Hakim's hypothesis because they showed that patients at the end of dialysis were not achieving levels at or often even near to bicarbonate concentration prescribed by the physician for the dialysate. The actual results for these patients were not close to the "total buffer" Dr. Hakim understood would have been provided to those patients. *See* Exhibits S, U, V, and W. In addition, the case required the attention of people at the company who were well versed not just in the treatment of patients by physicians but also who were involved in the development and creation of the machines and equipment used in the process.

By the Spring of 2013 Ben Lipps, the founder of FMCNA and eventual world-wide CEO of Fresenius, reviewed the allegations and the issues presented in these cases. Dr. Lipps is one of the most technically accomplished scientists in the history of hemodialysis. Dr. Lipps earned a Ph.D in chemical engineering from MIT, and went on to develop the first computer-controlled hemodialysis machine. Of particular import to this case, Dr. Lipps led the team that developed the first ever artificial hollow-fiber membrane for use in dialyzers. This is the very same semi-permeable membrane in use today over which bicarbonate and acetate diffuse during modern three-stream dialysis.

[5] A much more rigorous follow-on study, using the same raw data but making proper adjustments, concluded that "[c]onsistent with the primary analyses, dialysate total buffer and its bicarbonate component (separately) were not associated with CPA in either control-1 or control-2 secondary analyses." *See* Exhibit X (especially p. 5).

Upon learning of plaintiffs' theory of the case, including their reliance on Dr. Hakim's "total buffer" concept, Dr. Lipps realized that Dr. Hakim and others at FMCNA had overlooked a critical – but indisputable - scientific fact. They had simply neglected to account for the bi-directional nature of diffusion caused by a concentration gradient. As one of the world's leading membrane experts, Dr. Lipps understood that no matter how much acetate was metabolized into bicarbonate by a patient's liver, the concentration of bicarbonate in the patient's blood during dialysis could never exceed the concentration of bicarbonate in the dialysate. If the patient's serum bicarbonate concentration became greater than the bicarbonate concentration on the dialysate side of the membrane, the gradient would be reversed, and bicarbonate would pass out of the blood, into the dialysate, and be pumped to the drain. So while the amount of acetate a patient received might contribute to the ***rate*** at which serum bicarbonate approached the prescribed bicarbonate during dialysis, it could never cause it to ***exceed*** the prescribed bicarbonate level during dialysis.

Dr. Lipps asked Dr. Frank Gotch – a nephrologist and longstanding consultant to FMCNA -- to confirm his understanding. By coincidence in 2005, Dr. Gotch had previously performed theoretical modelling that embraced the "total buffer" mistake. Upon learning of Dr. Lipps's critique of "total buffer," Dr. Gotch revisited his prior model. Dr. Gotch thereafter (in April 2013) emailed Dr. Lipps:

> Attached find Acid Base Model from 2005. ***I am embarrassed to say you are right and I did not correctly describe acetate flux in the model. I lumped acetate and bicarb together*** in Cdi rather than describing the bicarb generation from acetate as appearing directly in ECW after metabolism of acetate. The original model is attached with error part in blue font. I am going to derive the correct flux equations and will resend a revised document with simulations.

See Exhibit Y. As promised, Dr. Gotch transmitted revised analyses to Dr. Lipps. In one instance, he referred to "total buffer" as an "erroneous understanding." *See* Exhibit Z. In

another, next to the earlier work where he had adopted the "total buffer" theory, Dr. Gotch wrote in large bolded letters "THIS WAS WRONG." *See* Exhibit AA.

FMCNA counsel subsequently presented Dr. Lipps's explanation to FMCNA employees who had previously accepted Dr. Hakim's view of "total buffer."[6] Those employees acknowledged they had overlooked the effect of the concentration gradient, and agreed that "total buffer" as espoused by Dr. Hakim was a mistake. Moreover, this fact explains previous post-dialysis testing by Fresenius, which showed over several years and in more than 20,000 instances that patients were not receiving total bicarbonate levels at the "total buffer" level hypothesized by Dr. Hakim.

At this point FMCNA realized that the "total buffer" language added to the product labels as part of the FDA recall and inserted into the operator's manual of its hemodialysis machines was inaccurate and potentially misleading. Embracing Dr. Hakim's view of "total buffer," the revised language suggested that a physician desiring a bicarbonate prescription of (for example) 34 mEq/L should order the machine to be set at 26 mEq/L, and could count on the 8 mEq/L of acetate provided by GranuFlo to make up the difference. As Dr. Lipps explained, though, this is scientifically impossible. If that patient's serum bicarbonate were to exceed 26 mEq/L during treatment, bicarbonate would move out of the patient's blood, across the membrane, and into the dialysate. The patient would ***not*** receive the prescription (34 mEq/L) that the treating physician had sought to deliver.

As a result, FMCNA sent letters to FDA explaining the misapplication of "total buffer" in writing, and requesting an in-person meeting to follow up. *See* Exhibits AB and AC. FDA agreed to an in-person meeting. At that meeting in May of 2014, FMCNA's new Chief Medical

[6] By this time Dr. Hakim had left FMCNA.

Officer Dr. Frank Maddux, supported by Dr. Kamyar Kalantar-Zadeh,[7] explained to FDA that Dr. Hakim's concept of "total buffer" was mistaken. FDA was represented at the meeting by eight individuals, including Dr. Frank Hurst, who is a medical doctor and board certified in internal medicine, as well as Gemma Gonzalez, who has for years been FDA's representative on the AAMI standards committee for hemodialysis products. After fully considering the issue, FDA agreed that the prior "total buffer" warning language it required FMCNA to add to the labels and product literature was inaccurate and inappropriate. With minor revisions, FDA agreed that FMCNA should remove the "total buffer" language from its product labels and product literature, because the "total buffer" concept was mistaken and potentially misleading. *See* Exhibit AD. FMCNA's new Chief Medical Officer has also issued a memorandum correcting the "total buffer" error. *See* Exhibit AE.

ARGUMENT

It is well settled that the moving party on a motion to compel bears the burden of demonstrating that the preservation and production efforts of the non-moving party were inadequate. *See Larsen v. Coldwell Banker Real Estate Corp.*, 2012 WL 359466, at *7-8 (C.D. Cal. Feb. 2, 2012) (denying motion to compel the production of documents where "Plaintiffs have failed to meet their burden of showing that Defendants' preservation and production of ESI was inadequate," and where "[t]he few isolated examples cited by Plaintiffs (out of a document production of approximately 9,000 pages) fail to demonstrate that Defendants have not reasonably and in good faith produced the documents required"). Plaintiffs should not be permitted to "undertake wholly exploratory operations in the vague hope that something helpful will turn up." *Mack v. Great Atlantic & Pacific Tea Co.*, 871 F.2d 179, 187 (1st Cir. 1989)

[7] Dr. Kalantar-Zadeh is a research and treating nephrologist and also one of the world's leading renal epidemiologists.

(motion to compel properly denied where "requiring [defendant] to cull through the personnel records of hundreds of employees, at scattered sites in differing labor markets, over a 4–year period, could plausibly have been viewed as 'unduly burdensome or expensive, taking into account the needs of the case'") (*citing* Fed.R.Civ.P. 26(b)(1)); *see also Rodriguez-Torres v. Gov't Dev. Bank of P.R.*, 265 F.R.D. 40, 44 (D.P.R. 2010) (rejecting motion to compel as abusive when it is "merely a fishing expedition to find out if there is any evidence that supports their claim"). Under Rule 26, the trial court is required to balance the burden of proposed discovery against the likely benefit." *Gill v. Gulfstream Park Racing Ass'n, Inc.*, 399 F.3d 391, 400 (1st Cir. 2005).

Here, Plaintiffs seek eight additional search terms applied to all of the information garnered from Dr. Gotch's library, including two laptop computers, plus an "eyes on" review of the hard copy materials contained in the 58 boxes that Dr. Gotch maintained and a log of all documents withheld on any grounds, including relevancy. Such a review is unnecessary to capture the relevant documents in Dr. Gotch's collection and is unnecessarily burdensome and time-consuming. FMCNA believes that the process for document review negotiated and agreed-upon with the Plaintiffs for all other custodians relevant to this litigation is reasonable and strikes the proper balance that Rule 26 seeks to achieve between the burden of the proposed discovery and its likely benefit. *See Amorim Holding Financeira S.G.P.S., S.A. v. C.P. Baker & Co., Ltd.*, 2011 WL 5879433, at *2 (D. Mass. Nov. 22, 2011) (denying plaintiff's motion to compel where "the burden of the proposed discovery will outweigh its likely benefit").

Indeed, courts have rejected motions to compel where, as here, a party has already run a search with search terms provided by opposing counsel. *See, e.g.*, *Whitlow v. Martin*, 2008 WL 2414830, at * 7 (C.D. Ill. June 12, 2008) (denying motion to compel where "[p]laintiff fail[ed] to

explain how a search with search terms provided by Plaintiff's counsel is insufficient"); *see also Harry M. v. Pa. Dept. of Pub. Welfare*, 2011 WL 53047, at * 2 (M.D. Pa. Jan. 7, 2011) (refusing to revisit the parties' discovery protocol agreement or to order the parties to add additional search terms where parties had conferred and agreed to a search protocol that included 27 search terms, and the court was "satisfied that [the] framework [was] sufficient to identify responsive documents"); *Capital Ventures Intern. v. J.P. Morgan Mortg. Acquisition Corp.*, 2014 WL 1431124, at * 3 (D. Mass. Apr. 14, 2014) (denying plaintiff's motion to compel expanded searches for an undefined number of additional employees "absent reasons to believe that a significantly wider search is likely to uncover more relevant documents . . .")

Here, the suggestion that Dr. Gotch's counsel should conduct a manual, page-by-page relevancy review of all 58 boxes that comprise his personal scientific library, as well as the voluminous material on two computer hard-drives, is unwarranted. FMCNA has collected all of Dr. Gotch's work relating to "total buffer," scanned all paper documents in word searchable format, and applied the parties' agreed-upon search terms against all collected materials. Non-privileged responsive documents from Dr. Gotch have been produced to Plaintiffs. In light of this, Plaintiffs are without any reasonable basis to argue that production efforts on behalf of Dr. Gotch have been deficient or inadequate.

Despite the production of documents, Plaintiffs aver that the burden attendant to applying eight additional search terms to the entire contents of two laptop computers and conducting a page-by-page relevancy review of 58 boxes of materials is *de minimis*, and also that "[t]he relatively minor effort and expense necessary to search two laptops and a few boxes of paper documents is inconsequential[.]" [brief at 18-19] These arguments are wrong. A manual review of 58 boxes of documents and two large computer hard-drives, along with the creation of a log

for each and every ***irrelevant, non-responsive*** document located during the review, would be an extremely costly and time-consuming undertaking.

Plaintiffs hinge their demands on a claim that Dr. Gotch is a central figure relative to the "total buffer" issue, and that he has for some unknown reason elected to withhold from FMCNA documents related to his work for FMCNA in this area. Neither of these claims is supportable. As explained above, Dr. Lipps simply used Dr. Gotch as a sounding board to confirm his conclusion that Dr. Hakim and others were mis-appyling diffusion principles relative to "total buffer." As he admitted, Dr. Gotch had made the same mistake some years earlier. All of these topics can be explored with Dr. Lipps at deposition, which is scheduled for January 29-30, 2015. Nor is there any indication whatsoever that Dr. Gotch failed to provide to FMCNA any work he performed relating to "total buffer." As one would expect, all indications are that he transmitted his work to FMCNA personnel. To the extent that he did not, any remaining responsive material would be captured by application of the agreed search terms, which include "buffer," "total buffer," "bicarbonate," "acetate," and "acidosis."

It is also true that Dr. Gotch's hard drives and personal library contain enormous amounts of material unrelated to this case. Dr. Gotch researched, educated and practiced in the nephrology field for 60 years. A copy of Dr. Gotch's 29-page CV is attached as Exhibit AF. He ran a dialysis unit at the University Of San Francisco Hospital. Consulting with FMCNA was never his main job. It should therefore come as no surprise that his computers and library appear to be comprised primarily of non-FMCNA related material. As can be observed from even a cursory glance at his publications (128 in total), his research interests extend far beyond acid-base balance. It would not be warranted to require a review of his documents on these subjects, which concededly have absolutely nothing to do with any issue in this case.

Plaintiffs wrongly argue that "Fresenius seeks to impermissibly and unilaterally decide what it believes are appropriate search terms and refuses to work with Plaintiffs to facilitate meaningful discovery of Dr. Gotch's files." [brief p. 20] This is facially wrong. FMCNA applied the ***agreed*** search terms that the parties negotiated, and which have been deemed sufficient for every other custodian in this case. Plaintiffs have made no showing whatsoever that the search terms - which have sufficed for every other purpose in this case – require special amendment here.

CONCLUSION

The Court should deny Plaintiffs' Motion in its entirety.

Respectfully submitted,

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Dated: December 16, 2014

CERTIFICATION OF SERVICE

I hereby certify that a true and correct copy of the foregoing document filed through the ECF system will be sent electronically to the registered participants as identified on the Notice of Electronic Filing (NEF) and paper copies will be sent to those indicated as non-registered participants on December 16, 2014.

/s/ William H. Kettlewell
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